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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------|-------------|-----------------------------------|---------------------|------------------|
| 10/525,959 | 02/28/2005 | Lucas Cyril Gerard Van Der Heyden | 4662-2 | 3062 |
| 23117 | 7590 | 12/23/2005 | EXAMINER | |
| NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | | AUDET, MAURY A |
| ART UNIT | | PAPER NUMBER | | |
| | | 1654 | | |

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/525,959 | VAN DER HEYDEN ET AL. | |
| | Examiner | Art Unit | |
| | Maury Audet | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The present application is 371 of PCT/EP03/09790. The related International Search Report and Written Opinion therefrom covers virtually identical claims as presented here (other than a preliminary amendment to remove multiple dependencies). In Box I.2 of the Search Report it was indicated that “claims 1-18 relate to compositions, uses and methods involving a compound defined by reference to a desirable characteristic or property, namely sensitizing to insulin. [] In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. []A compound cannot be sufficiently defined by its mechanism of action and/or its pharmacologic profile.” The International Authorities struggle with the search of the invention based on the claim language/application as filed, is evidenced by the 17 references cited therein, each reading all or in part over the claims. and search thereof.

Notwithstanding the difficulty in searching structure-based subject matter, which is at the core of the present invention, which has been claimed by language to said structures mechanism of action and/or pharmacologic profile; a reasonable and diligent attempt has been made to search/examine the invention as claimed; similar to the problem faced by the International Searching/Examining Authority,. Claims 1-18 are herein examined on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated WO 01/00223 A2 (Minimed Inc.).

WO 01/00223 A2 teaches a composition comprising an insulin sensitizer (abstract, pages 5-7, claim 1) and peptide fraction (in the form of an insulin fragment; abstract, pages 5-7, and claims).

Claims 1, 17 and 18 are also rejected under 35 U.S.C. 102(b) as being anticipated WO 01/00223 A2 (Minimed Inc.).

WO 01/00223 A2 teaches a method of treating diabetes type 2 comprising a composition (of claim 1) comprising an insulin sensitizer (abstract, pages 5-7, claim 1) and peptide fraction (in the form of an insulin fragment; abstract, pages 5-7, and claims). [It is noted that Applicant's specification page 8, line 12 indicates that "all type of peptides" are encompassed in the label "peptide fraction"].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/00223 A2 (Minimed Inc.) in view of Van Loon et al. (US 6,713,082 B2)

WO 01/00223 A2 is discussed above. The reference does not expressly teach the peptide fraction as hydrosylated, comprising free amino acids, or the size limitations of the peptide fraction.

Van Loon et al. teach a composition to enhance blood insulin response comprising a peptide material, free amino acids selected from Leu and Phe, and size limitations of the peptide material (abstract, claims, entire document)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the peptide fractions/sizes and free amino acids in the composition of WO 01/00223 A2, because Van Loon et al. advantageously teach such peptide fractions/sizes, free amino acids in a composition for enhancing blood insulin response and because WO 01/00223 A2 similarly teach compositions comprising peptide fragments which enhance blood insulin response (e.g. in diabetic therapy).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 U.S.C. § 112 1st Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while (potentially, upon claim amendment) being enabling for treating type 2 diabetes [in a subject in need thereof for], does not reasonably provide enablement for *preventing* the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Applicants have (potentially) reasonably demonstrated/disclosed that the claimed invention may be used for treating an individual who has type 2 diabetes. However, the claims also encompass using the claimed composition to prevent the same, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such disorders as diabetes (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition which would function to prevent type 2 diabetes..

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18, as discussed in the opening of this Action (and by the International Authority), fail to particularly point out and distinctly claim the subject matter to which the

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invention is drawn. Generic claims covering an invention are permissible, so long as the invention can be ascertained therefrom. However, based on the present claim language, one of skill in the art would not be reasonably apprised of what constitutes the invention or what products/methods would read thereupon. It is suggested that Applicant amend the claims to particularly point out and distinctly claim the subject matter to which the invention is drawn. [The claims so lacking clarity it is not clear whether a 112 1st para. Written Description or Enablement/Scope thereof, presently exist. Therefore rejections under the 1st paragraph are hereby held in abeyance until the claims have been amended such that a determination under 112 1st can be made].

Claim s 14-16 provides for the use of a composition comprising a peptide fraction”, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Thus, the claims have only been examined as being drawn to the product.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 12/09/2005



CHRISTOPHER R. TATE
PRIMARY EXAMINER